

## **REMARKS**

In the Office Action mailed on June 3, 2005, the Examiner rejected claims 1-7 and 9-12. Specifically, the Examiner rejected claims 1-5 and 11-12 under 35 U.S.C. § 102. Additionally, the Examiner rejected claims 1-7 and 9-12 under 35 U.S.C. § 103. Further, the Examiner rejected claim 11 based on the judicially created doctrine of obviousness-type double patenting. Claims 6 and 11 are presently amended to clarify certain aspects of the present invention. Applicants request reconsideration of claims 1-7 and 9-12 in view the amendments set forth above and the following remarks.

### **Claim Rejections under 35 U.S.C. § 102**

In the Office Action, the Examiner rejected claims 1-5 and 11-12 under 35 U.S.C. § 102(b) as anticipated by Sakai et al. (U.S. Patent No. 4,942,877). Applicants respectfully traverse this rejection. Specifically, with regard to the independent claims the Examiner stated:

Sakai teaches a light emitter 20, a detector 25, and a memory 56. (Fig. 1 of Sakai). Claims 1-5 and 11-12 recite limitations that attempt to claim particular data that is stored in the memory. A memory only stores data in the forms of 1's and 0's and such data are not structurally distinct from any other data that are stored as 1's and 0's. It is the connection to the microprocessors that provide meaning to the data in the memory. Without this connection to provide meaning to the data, there is not structural distinction from one data set to another.

Office Action, page 2.

Anticipation under 35 U.S.C. § 102 can be found only if a single reference shows exactly what is claimed. *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 U.S.P.Q. 773 (Fed. Cir. 1985). For a prior art reference to anticipate under 35 U.S.C. § 102, every element of the claimed

invention must be identically shown in a single reference. *In re Bond*, 910 F.2d 831, 15 U.S.P.Q.2d 1566 (Fed. Cir. 1990). To maintain a proper rejection under 35 U.S.C. § 102, a single reference must teach each and every limitation of the rejected claim. *Atlas Powder v. E.I. du Pont*, 750 F.2d 1569 (Fed. Cir. 1984). Accordingly, the Applicants need only point to a single element not found in the cited reference to demonstrate that the cited reference fails to anticipate the claimed subject matter.

Further, when a computer program is recited in conjunction with a physical structure, such as a computer memory, Office personnel should treat the claim as a product claim. M.P.E.P. § 2106(IV)(B)(1)(a). Indeed, such data stored on a general purpose device renders the general purpose device a “new machine.” *Cf. In re Alappat*, 31 U.S.P.Q.2d 1545, 1555-58 (“[A] general purpose computer becomes a special purpose computer once it is programmed.”). A claimed computer-readable medium encoded with a computer program is a computer element which defines structural and functional interrelationships between the computer program and the rest of the computer which permit the computer program’s functionality to be realized, and is thus statutory. M.P.E.P. § 2106(IV)(B)(1)(a). All words in a claim must be considered in judging the patentability of that claim against the prior art. *In re Wilson*, 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970); *see* M.P.E.P. § 2143.03.

Turning to the claims, independent claim 1 recites, *inter alia*, “[a]n oximeter sensor comprising ... a memory storing a first set of coefficients corresponding to a wavelength of said light emitter for use in a first formula for determining oxygen saturation, and a second set of coefficients corresponding to said wavelength of said light emitter for use in a second, different

formula for determining oxygen saturation.” As amended, independent claim 11 recites, *inter alia*, “[a]n oximeter sensor comprising ... a memory storing a plurality of alternate values of oxygen saturation or ratio-of-ratio values used in at least two different equations to determine oxygen saturation, said plurality of values corresponding to the same mean wavelength of said same light emitter.” In summary, each of the independent claims relates to a sensor memory storing data that facilitates determining oxygen saturation in a patient.

Applicants respectfully assert that by storing information relating to determining oxygen saturation within a memory of a sensor, as recited in the present claims, the memory becomes a new machine. Accordingly, the mere disclosure of a *sensor having a memory* fails to anticipate the present claims. Specifically, Applicants assert that the Sakai reference’s disclosure of a probe having a memory circuit is not sufficient to anticipate the present claims because all of the claimed features are not present. In contrast to the present claim recitations, the Sakai reference merely teaches a probe 1 having a red light emitting diode (RLED) 20, an infrared light emitting diode (IRLED) 21, a light receiving element 25, and a memory circuit 56 that stores “eleven items with respect to the *properties of the light or ray* of the RLED 20 and the IRLED 21.” Sakai et al., col. 3, lines 13-58 (emphasis added). Applicants assert that the Sakai reference is deficient because none of these eleven stored items correspond to the features relating to *determination of oxygen saturation* recited in the present claims. Indeed, the Examiner recognized the deficiency of the Sakai reference, yet ignored the claim language that distinguishes over the Sakai reference.

For the reasons set forth above, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 102 of independent claims 1 and 11, and the claims depending therefrom.

Further, Applicants request that the Examiner provide an indication of allowance for independent claims 1 and 11, and the claims depending therefrom.

### **Rejections Under 35 U.S.C. § 103**

The Examiner rejected claims 1-4, 6, 7, 9, 11 and 12 under 35 U.S.C. § 103(a) as being unpatentable over Sperinde (U.S. Pat. No. 4,623,248) in view of the Sakai reference. Further, the Examiner rejected claims 1-3, 5-7, 10 and 11 under 35 U.S.C. § 103(a) as being unpatentable over Kofsky et al. (U.S. Pat. No. 4,086,915) in view of the Sakai reference. Specifically, with regard to the independent claims the Examiner stated:

Sperinde discloses an oximeter in which the oxygen saturation level is computed by using a formula which uses the ratio of one pair of intensity signals when the oxygen saturation level is relatively low and with another formula which uses the ratio of another pair of intensity signals when the oxygen saturation level is relatively high. (Abstract of Sperinde). Each formula has a different set of coefficients. Sperinde does not disclose a sensor memory, which stores the coefficients and thresholds for use in the formulas. However, the method of Sperinde requires the calibrated coefficients and data (including thresholds) to be stored in a memory to carry its steps since the coefficients need to be recalled for various different measurements over time. Sakai discloses a memory used to store coefficients and calibration data (including thresholds) for the determination of oxygen saturation. The memory is located in the sensor unit. (column 12, lines 6-37 of Sakai). Such a memory would fulfill the requirement of the necessary storage of the coefficients and calibration data (including thresholds) in the invention of Sperinde. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the memory of Sakai in the invention of Sperinde since the invention of Sperinde requires a device for data storage of the coefficients and calibration data and Sakai et teaches one such method. In regard to claim 1, Sperinde teaches a light emitter and light detector. (Fig. 4 of Sperinde). ... In regard to claims 3 and 6, Sperinde discloses a threshold point in the form of

saturation values for determining which of the two formulas to use. (column 5, line 46 to column 6, line 7 of Sperinde).

Kofsky et al. teaches an oximeter with multiple sets of coefficients for use in calculating oxygen saturation depending on the range of total hemoglobin concentration. (column 8, lines 8-24 of Kofsky et al.). The different hemoglobin concentrations would cause different saturation readings for a particular set of coefficients. Kofsky et al. does not teach that the coefficients are stored in the sensor. It is well known in the art to use memories in sensors to store coefficients and calibration data (including thresholds). (column 12, lines 6-37 of Sakai et al.). Placing sensor-specific threshold values in the memory of a particular sensor would allow more accurate calculations while removing the need to store the calibration values in the oximeter for a plurality of different sensors, i.e., different sensors can then be used with the oximeter. Further, Sakai et al. suggests that the coefficients and calibration data (including thresholds) used in calculating oxygen saturation can be stored in either the sensor or in the main unit. (column 12, lines 6-37 of Sakai et al.). This suggestion implies that placing the calibrated coefficients and data in the sensor memory is functionally equivalent to placing the calibrated coefficients in the memory of the main unit. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the sensor of Kofsky et al. to include a memory in the sensor as disclosed by Sakai et al. since sensor-specific calibration values in the memory of a particular sensor would allow more accurate calculations while removing the need to store the threshold value in the oximeter for a plurality of sensors and Sakai implies that using a memory in the sensor is functionally equivalent to using a memory in the main unit. In regard to claim 1, the combination teaches a light source 1, a light detector 9 (Fig. 1 of Kofsky), a memory (column 12, lines 6-37 of Sakai et al.), and storing multiple sets of coefficients for use in calculating oxygen saturation depending on the range of total hemoglobin concentration. (column 8, lines 8-24 of Kofsky et al.). The selection of the coefficients depends upon the values obtained from the light detector 9. In regard to claims 5-6 and 10, the combination teaches a plurality of coefficients  $P_i$  and provides an example of four sets. (column 8, lines 8-24 of Kofsky et al.).

Office Action, pages 3-5.

The burden of establishing a *prima facie* case of obviousness falls on the Examiner. *Ex parte Wolters and Kuypers*, 214 U.S.P.Q. 735 (P.T.O. Bd. App. 1979). To establish a *prima facie* case of obviousness, the Examiner must not only show that the combination includes *all* of the claimed elements, but also a convincing line of reason as to why one of ordinary skill in the art would have found the claimed invention to have been obvious in light of the teachings of the references. *Ex parte Clapp*, 227 U.S.P.Q. 972 (Bd. Pat. App. & Inter. 1985). A statement that the proposed modification would have been “well within the ordinary skill of the art” based on individual knowledge of the claimed elements cannot be relied upon to establish a *prima facie* case of obviousness without some *objective reason to combine* the teachings of the references. *Ex parte Levengood*, 28 U.S.P.Q.2d 1300 (Bd. Pat. App. & Inter. 1993); *In re Kotzab*, 217 F.3d 1365, 1371, 55 U.S.P.Q.2d 1313, 1318 (Fed. Cir. 2000); *Al-Site Corp. v. VSI Int’l Inc.*, 174 F.3d 1308, 50 U.S.P.Q.2d 1161 (Fed. Cir. 1999).

A prior art reference that “teaches away” from the claimed invention is a significant factor to be considered in determining obviousness. *See* M.P.E.P. § 2146(X)(1). Additionally, it is improper to combine references where the references teach away from their combination. *In re Grasselli*, 713 F.2d 731, 743, 218 U.S.P.Q. 769, 779 (Fed. Cir. 1983); M.P.E.P. § 2145. Moreover, if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 U.S.P.Q. 349 (C.C.P.A. 1959); *see* M.P.E.P. § 2143.01.

Applicants respectfully assert that the Examiner's rejection of claims 1-4, 6, 7, 9, 11 and 12 as obvious over the Sperinde reference in view of the Sakai reference was improper. Indeed, Applicants assert that the Sperinde and Sakai references, whether considered together or separately, do not teach all of the features of independent claims 1, 6, and 11. For example, claim 1 recites, *inter alia*, "a memory storing ... a first set of coefficients corresponding to a wavelength of said light emitter ... and a second set of coefficients corresponding to said wavelength of said light emitter." Claims 1 and 11 were previously amended to clarify that the coefficients are for different formulas for the *same* wavelength of the *same* light emitter. Further, claim 6 is presently amended to include this feature.

Applicants previously asserted and maintain that the Sperinde reference fails to teach using different formulas for the *same* sensor element or light emitter, as presently claimed. However, as set forth in the Response to Arguments portion of the Office Action, the Examiner disagreed. Specifically, the Examiner stated:

The Applicant wishes to distinguish between Sperinde's use of Equation (1), which uses wavelengths 2 and 3, and Equation (5), which used wavelengths 1, 2, and 3. The use of wavelength 1 in one of the formulas is irrelevant to the fact that the same wavelength (2 or 3) is used in two different formulas. The claim language does not preclude the use of an additional wavelength (1) in one of the two formulas.

Office Action, page 7.

Applicants respectfully assert that the Sperinde reference does not teach using different formulas for the same sensor element or light emitter. The Sperinde reference discloses that two

different equations (1) and (5) *with different variables* are used for oxygen saturation level computation depending upon whether the oximeter is in the arterial mode or venous mode. *See* Sperinde, col. 6, lines 36-68. It is apparent from the disclosure of the Sperinde reference that each of these two equations (1) and (5) are calculated based on the use of *different wavelengths*. *See id.* at col. 3, lines 1-62. Accordingly, Applicants stress that the Examiner's assertion of equivalence between wavelengths 2 and 3 of equation (1) and wavelengths 2 and 3 of equation (5) is inaccurate.

The wavelengths corresponding to equations (1) and (5) of the Sperinde reference are separately defined for each equation. With respect to equation (1), the Sperinde reference teaches that wavelength 3 is "usually an isosbestic wavelength" and wavelength 2 is "a non-isosbestic wavelength." *See id.* at col. 2, lines 35-40. In contrast, equation (5) appears to be a completely different equation corresponding to completely different wavelengths. *See id.* at col. 3, lines 1-27. Indeed, regarding equation (5), the Sperinde reference teaches that the three wavelengths 1, 2, and 3 are approximately 670 nanometers, 700 nanometers, and 800 nanometers. *See id.* at col. 3, lines 53-62. In view of these distinctions, equation (1) and equation (5) of the Sperinde reference are apparently separate equations that do not share variables. Accordingly, while equations (1) and (5) of the Sperinde reference may share nomenclature, the Sperinde reference fails to teach using different formulas for the *same* sensor element or light emitter. Further, the Sakai reference fails to remedy this deficiency. Indeed, the Examiner merely cited the Sakai reference for its teaching of a sensor memory.



Additionally, Applicants respectfully assert that the Examiner's rejection of claims 1-3, 5-7, 10 and 11 as obvious over the Kofsky reference in view of the Sakai reference was improper. Indeed, Applicants assert that the Kofsky and Sakai references, whether considered together or separately, do not teach all of the features of independent claims 1, 6, and 11. Independent claim 1 and amended independent claims 6 and 11 each recite features relating to storing different sets of coefficients with *different equations* for the same wavelength and light emitter within a sensor memory to facilitate calculation of oxygen saturation. For example, independent claim 1 recites, *inter alia*, "a memory storing a first set of coefficients corresponding to a wavelength of said light emitter for use in *a first formula* for determining oxygen saturation, and a second set of coefficients corresponding to said wavelength of said light emitter for use in *a second, different formula* for determining oxygen saturation." (Emphasis added).

In contrast to the present claims, the Kofsky reference apparently teaches the use of a *single* equation with different sets of coefficients, depending on total hemoglobin concentrations in a subject. *See* Kofsky et al., col. 8, lines 10-31. Specifically, the Kofsky reference states that "different coefficients  $P_i$  can be used for different ranges of total hemoglobin concentration." Kofsky et al., col. 8, lines 13-14. Indeed, according to the Kofsky reference, "The set of  $P_i$  coefficients most appropriate for the subjects total hemoglobin concentrations is used for *the computations*." *Id.* at col. 8, lines 19-22 (emphasis added). Accordingly, Applicants respectfully assert that Kofsky fails to teach first and second formulas that are different and have different coefficients for determining oxygen saturation. Additionally, the Sakai reference fails to remedy this deficiency. Indeed, the Examiner merely cited the Sakai reference for its teaching of a sensor memory.

Further, the Kofsky reference teaches away from the present invention and teaches away from combination with the Sakai reference. Indeed, the Kofsky reference teaches that coefficients should be stored in computer sections of *oximeters*, not within a sensor memory. Specifically, the Kofsky reference states, “Since these coefficients will be stored in the computer sections of the oximeter, it will be very simple to use them.” Kofsky, col. 8, lines 23-25. Because the Kofsky reference teaches that the coefficients should be stored in the computer sections of an oximeter, there would be no reason to suggest that the coefficients be stored in a sensor memory, as recited in the present claims. Indeed, the Kofsky reference suggests quite the opposite. Accordingly, not only does the Kofsky reference teach away from the present invention, it teaches away from combination with the sensor memory of the Sakai reference.

For the reasons set for above, the Applicants respectfully request withdrawal of the rejections under 35 U.S.C. § 103. Specifically, Applicants request that the Examiner withdraw the rejection of independent claims 1, 6, and 11, and the claims depending therefrom. Further, Applicants request that the Examiner provide an indication of allowance for independent claims 1, 6, 11, and the claims depending therefrom.

### **Double Patenting**

The Examiner rejected claim 11 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 8 of U.S. Patent No. 6,801,797. Although Applicants do not agree with the Examiner’s rejection and respectfully assert that amendments to 35 U.S.C. § 1.54 obviate the necessity of a terminal disclaimer on any claims issuing from an

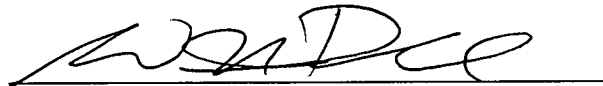
application claiming a priority under 35 U.S.C. § 120, Applicants submit a properly executed terminal disclaimer attached hereto as Appendix A. Applicants respectfully submit that the terminal disclaimer obviates the Examiner's obviousness-type double patenting rejection.

**Conclusion**

In view of the remarks set forth above, Applicant respectfully requests allowance of claims 1-7 and 9-12. If the Examiner believes that a telephonic interview will help speed this application toward issuance, the Examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

Date: October 3, 2005



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